UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RONALD L. REAM, CHRISTINE L. CORRIVEAU, WILLIAM J. WOKAS, THOMAS M. TONGUE JR., and MICHAEL J. GREENBERG

Appeal No. 2004-1722
Application No. 09/286,818

ON BRIEF

Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-12 and 19-22, all of the claims remaining. Claim 1 is representative and reads as follows:

1. A method for delivering a medicament to an individual comprising the steps of: providing a chewing gum consisting of ingredients selected from the group consisting of elastomers, resins, fats, oils, softeners, fillers, waxes, colorants, antioxidants, plasticizers, texturizers, emulsifiers, whiteners, acidulants, bulking agents, essential oils, sweeteners, and flavors, and at least one medicament, the ingredients and medicament having a uniform distribution throughout the chewing gum including less than the typical amount of medicament that is swallowed by the individual to achieve an effect;

chewing the chewing gum to cause the medicament to be released from the chewing gum composition into the buccal cavity of the individual; and

continuing to chew the chewing gum thereby creating a fluid pressure causing the medicament to enter the systemic system of the individual through an oral mucosa of the individual.

The examiner relies on the following references:

Cherukuri et al. (Cherukuri)	5,013,716	May 07, 1991
Häusler et al. (Häusler)	5,922,347	Jul. 13, 1999

Claims 1-12 and 19-22 stand rejected under 35 U.S.C. § 103 as obvious in view of Cherukuri and claims 1, 7, and 19 stand rejected under 35 U.S.C. § 103 as obvious in view of Cherukuri and Häusler.

We vacate the examiner's rejections and enter a new ground of rejection under 35 U.S.C. § 112, second paragraph.

Background

The specification discloses administration of medicaments using chewing gum formulations:

> [C]hewing gum is provided including a medicament or agent. . . . It has been found that by chewing the gum, the medicament or agent is released from the chewing gum. Continuing to chew the chewing gum creates a pressure within the buccal cavity forcing the agent or medicament directly into the systemic system of the individual through the oral mucosa contained in the buccal cavity. This greatly enhances the absorption of the drug into the systemic system as well as the bioavailability of the drug within the system.

Page 4. See also page 8: "[L]ess medicament or agent can be placed in the chewing gum than is typically orally administered to an individual to achieve an effect and the same bioequivalence can be achieved."

Discussion

The claims are directed to a method of administering a medicament via chewing gum. Each of the independent claims (claims 1, 7, and 19) includes the limitation that the chewing gum contains "less than the typical amount of medicament [or agent, claim 7] that is swallowed by [an] individual to achieve an effect."

The examiner rejected the claims as obvious. The examiner did not point to anything in the references meeting the "less than the typical amount" limitation, but instead asserted that "since applicant has not defined the 'typical amount', the examiner cannot establish the patentability distinct between 'less than a typical amount' and 'ordinary amount' disclosed by Cherukuri." Examiner's Answer, page 5. See also page 7: "Again, the examiner has been unable to compare 'less than a typical amount' and 'ordinary amount' taught by Cherukuri and Hausler. Thus, it is the position of the examiner that no patentability distinct [sic, patentable distinction?] can be seen in the particular limitation, because 'less than a typical amount' can be any ordinary amount."

Thus, the examiner essentially ignored the "less than the typical amount" limitation, on the basis that that limitation had no defined meaning. This is not the correct way to treat an undefined limitation. "All words in a claim must be considered in judging the patentability of the claim against the prior art. If no reasonably definite meaning can be ascribed to certain terms in the claim, the subject matter does not become obvious—the claim becomes indefinite." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Since the examiner has not considered the claimed "subject matter as a whole," as required by 35 U.S.C. § 103, we vacate the rejections on appeal.

New Ground of Rejection

Under the provisions of 37 CFR § 1.196(b), we make the following new ground of rejection: claims 1-12 and 19-22 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite.

As noted above, each of the pending independent claims (claims 1, 7, and 19) includes the limitation that the chewing gum contains "less than the typical amount of medicament [or agent, claim 7] that is swallowed by [an] individual to achieve an effect." Claims 2-6, 8-12, and 20-22 also incorporate that limitation by virtue of their dependence on claim 1, 7, or 19.

The specification does not define what amount of a medicament or agent is "the typical amount" swallowed to achieve an effect. Nor does it appear from the record that those skilled in the art would have recognized a single dosage as "the typical amount" of a medicament administered.

Take aspirin, for example. At the time the instant application was filed, aspirin was available over the counter in at least three dosage forms: 81 mg/tablet, 325 mg/tablet, and 500 mg/tablet. See the 1996 Physician's Desk Reference, page 2455 (attached). We can take judicial notice of the fact that aspirin is typically swallowed two tablets at a time, which would correspond to administration of 162, 650, and 1000 mg, respectively, for the common dosage forms. Thus, 81 mg, 162 mg, 325 mg, 500 mg, 650 mg, and 1000 mg all appear to be "typical" amounts of aspirin to be swallowed to achieve an effect.

The claims, however, define the upper limit of medicament or agent that can be administered in the claimed method as "the" typical amount of medicament or agent. At

the same time, the specification does not define which of the six typical aspirin dosages, for example, is "the" typical dosage that defines the scope of the claims.

"The Supreme Court explained the reason underlying the indefiniteness doctrine 60 years ago in United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 236, 55 USPQ 381, 385 (1942):

> A zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field. Moreover, the claims must be reasonably clear-cut to enable courts to determine whether novelty and invention are genuine.

Exxon Research and Eng'g Co. v. United States, 265 F.3d 1371, 1375, 60 USPQ2d 1272, 1276 (Fed. Cir. 2001).

"The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, e.g., competitors of the patent owner, can determine whether or not they infringe." All Dental Prodx LLC v. Advantage Dental Products, Inc., 309 F.3d 774, 779-780, 64 USPQ2d 1945, 1949 (Fed. Cir. 2002). "A claim is indefinite if, when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1342, 65 USPQ2d 1385, 1406 (Fed. Cir. 2003).

In this case, the claims do not reasonably apprise those skilled in the art of the scope of the claimed method, and therefore they do not comply with the requirements of 35 U.S.C. § 112, second paragraph.

Appellants argue that the term "typical amount" is sufficiently clear. See the Appeal Brief, page 12.[1] Appellants reason that

> the specification provides that less medicament or agent can be placed in the chewing gum than is typically orally administered (e.g., swallowed). . . . Further, the specification provides that most orally administered drugs (e.g., medicaments) are in the form of tablets or capsules. See, specification, page 2, line[] 19. Indeed, Appellants conducted an experiment to compare the caffeine delivery effects between chewing gum pieces with 50 mg of caffeine . . . and chewable No-Doz® tablets with 100 mg of caffeine. . . . In view of same, one skilled in the art would recognize that the chewing gum as claimed includes an amount of medicament, such as caffeine, that is less than an amount of the same medicament as swallowed, such as via oral administration in the form of a tablet or capsule.

Id.

This argument is not persuasive. The specification provides no explanation of why an oral dosage of 100 mg of caffeine was chosen for comparison with 50 mg of gum-delivered caffeine. Even assuming, therefore, that "the typical amount" of caffeine administered is 100 mg, the specification provides no basis on which to extrapolate that dosage to other agents or medicaments.

Appellants also argue that "[w]hat is typically administered to achieve an effect or to treat a disorder is of course known to those skilled in the art. . . . Appellants[']claimed invention is treating the same disorder or achieving the same effect with less than that amount." Reply Brief, page 2.

This argument is also not persuasive. We can agree that typical dosage ranges are well-known in the art for common medicaments and agents. For example, as

[1] The examiner's final rejection included a rejection under 35 U.S.C. § 112, second paragraph, on the basis that "typical amount" was indefinite. The rejection was not repeated in the Examiner's Answer.

explained above, the typical dosage of aspirin ranges from 81 milligrams to 1000 milligrams. The problem with the present claims is that they purport to limit the amount of medicament or agent by referring to a single, specific dosage – the typical amount of medicament or agent swallowed to achieve an effect. The specification provides no definition or guidance regarding how to select a single dosage, from within the range of typical dosages, that represents "the typical amount of medicament [or agent] that is swallowed by [an] individual to achieve an effect."

Other Issues

1. Aspergum

As discussed above, typical dosages of aspirin include 325 mg, 500 mg, 650 mg, and 1000 mg. Aspergum® is a commercially available pain reliever in the form of gum tablets containing 227 mg of aspirin per tablet. See the attached advertisement from the web site www.drugstore.com. If the issue of claim definiteness is resolved after further prosecution, the examiner should consider whether Aspergum® meets the limitations of the product recited in the instant claims and whether it was commercially available as of this application's effective filing date. If so, a rejection under 35 U.S.C. § 103 may be appropriate.

2. Gudas

An application related to the present application was the subject of an earlier appeal to this board (application 09/671,552; Appeal No. 2003-1425). The claims in that appeal were directed to a method of administering a stimulant, such as caffeine, via chewing gum, and included the same "less than the typical amount" limitation of the instant claims. The claims had been rejected as obvious in view of a reference to

Gudas (WO 98/23165). The rejections were affirmed, and the panel in that appeal noted that Gudas "includes examples wherein the level of caffeine in the chewing gum product is about 0.1%, which is less than the level of caffeine found in a conventional cup of coffee."

The instant specification defines "agents" as "includ[ing], inter alia, stimulants such as caffeine." Page 8. If this application is subject to further prosecution, the examiner should consider the effect of Gudas on the patentability of at least claims 7-12, which are directed to a method of administering an agent via chewing gum.

Summary

We vacate the examiner's rejection and enter a new rejection under 35 U.S.C. § 112, second paragraph, because we are unable to determine the scope of the claimed method.

VACATED, 37 CFR § 1.196(b)

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